

Lioresal[®] Intrathecal

Baclofen 0.05 mg/1 mL Solution for Intrathecal Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Lioresal Intrathecal.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine. You can also download the most up-to-date leaflet from www.medsafe.govt.nz

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Lioresal Intrathecal against the benefits they expect it will give you.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Lioresal Intrathecal is used for

Lioreasal Intrathecal is used to reduce tension in your muscles which causes spasms. These spasms happen in various illnesses such as multiple sclerosis, cerebral palsy and other diseases or injuries of the spinal cord or brain.

Because this medicine reduces spasms and the pain that goes with

them, it helps to make you more mobile. This helps you to manage your daily activities and makes physiotherapy easier.

Lioreasal Intrathecal belongs to a group of medicines called muscle relaxants. It contains the active ingredient, baclofen, in the form of an ampoule for injection. It is used when medicines taken by mouth do not work well enough or when they cause too many side effects.

The solution in the ampoule is injected into your back, around your spinal cord. This medicine can be used for adults and for children aged four years or older.

There is no information on Lioresal Intrathecal in children under 4 years of age.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another purpose.

This medicine is only available with a doctor's prescription.

Before you have Lioresal Intrathecal

When you must not have it

Do not use Lioresal Intrathecal if you have ever had an allergic reaction after using or taking:

- baclofen (the active ingredient in Lioresal Intrathecal and Lioresal tablets)
- any of the other ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include hives or an itchy skin rash, flushing of the face, swelling of the face, lips or tongue, faintness,

tight feeling in the chest, wheezing or difficulty breathing.

Do not use Lioresal Intrathecal after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to have it

Tell your doctor if you are pregnant or breastfeeding. Ask your doctor about the risks and benefits involved.

There is no information on use of this medicine in pregnancy or while breast-feeding.

Tell your doctor if you have any of the following medical conditions:

- an infection of any kind
- epilepsy (seizures)
- a mental illness, especially if it makes you feel confused at times
- If you have thoughts of suicide or self-harm at any time. Speak to your doctor immediately or go to the Emergency Department of the nearest hospital for help. Ask your family, a friend or carer to monitor your behaviour and tell you if they are worried about any changes in your behaviour. Ask them to read this leaflet.
- heart disease
- kidney disease
- liver disease
- breathing problems
- stomach ulcers now or at any time in the past
- Parkinson's disease
- problems with blood flow to the brain.

Your doctor may not want to give you this medicine or may want to take special precautions if you have any of the above conditions.

If you have not told your doctor about any of these things, tell him/her before you start Lioresal Intrathecal.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Lioresal Intrathecal may interfere with each other. These include:

- medicines that lower blood pressure including medicines used to treat high blood pressure
- medicines to help you sleep or calm you down
- medicines for depression (sad mood)
- medicines for pain such as morphine
- medicines for Parkinson's disease.

You may need to take different amounts of your medicines or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are having Lioresal Intrathecal.

How Lioresal Intrathecal is given

What will happen

This medicine can only be given by experienced doctors using special medical equipment. You will need to stay in hospital, at least at the beginning of treatment.

Your doctor will inject a small amount of Lioresal Intrathecal into your spinal cord to see if it improves your muscle spasms.

If it does, then a special pump will be implanted under the skin of your abdomen. The pump will give you a small amount of medicine all the time.

You will be monitored closely in a fully equipped and staffed environment during the screening phase and dose-titration period immediately following pump implant. Lioresal Intrathecal is used for the screening phase. For more information on the use of baclofen after the screening phase, please speak with your health care professional.

If you have too much (Overdose)

Immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to the Accident and Emergency Department at your nearest hospital if you think that you may have had too much Lioresal Intrathecal, even if there are no signs of discomfort or poisoning.

It is very important that you and those caring for you know the signs of overdose that can happen. These are:

- unusual muscle weakness
- unusual sleepiness
- unusual light-headedness or dizziness
- unusual nausea or vomiting
- excessive saliva
- breathing problems
- fainting or fits (seizures)
- loss of consciousness
- abnormal low body temperature
- fast heartbeat
- ringing in the ears.

If you have any of the above signs, inform your doctor without delay.

Signs of overdose may happen suddenly or more slowly (for example, because the pump is not working properly).

If the medicine must be stopped

If this medicine must be stopped for any reason, your doctor will reduce the dose gradually to avoid unwanted side effects.

While you are having Lioresal Intrathecal

Things you must do

If your muscle spasms come back, either suddenly or gradually, tell your doctor.

Your doctor may be able to change the dose of your medicine to make it work better for you.

Tell your doctor immediately if you have pain in your back, shoulders, neck and buttock during treatment.

If you become pregnant while you are having this medicine, tell your doctor.

Your doctor can discuss with you the risks of being given this medicine while you are pregnant.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are having Lioresal Intrathecal.

Tell any other doctor, dentist or pharmacist who treats you that you are having Lioresal Intrathecal.

If you need to have a general anaesthetic, tell your doctor that you are treated with Lioresal Intrathecal.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem to be the same as yours.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you

are having Lioresal Intrathecal until you know how it affects you.

This medicine may cause dizziness, sleepiness or blurred vision in some people.

Be careful when drinking alcohol while you are having this medicine.

You may feel more sleepy or dizzy than usual.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are having Lioresal Intrathecal.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- drowsiness, tiredness or lack of energy
- dizziness or light-headedness
- headache
- feeling sick or vomiting
- loss of appetite, weight loss
- constipation
- numbness or tingling in the hands and feet
- muscle weakness, spasms or pain
- problems with coordination and balance
- slurred speech
- blurred or double vision
- feeling anxious, confused, disorientated or unable to sleep
- problems with concentration or memory
- dry mouth, decreased sense of taste

- diarrhoea
- increase in saliva
- problems with sexual function
- hair loss.

Tell your doctor immediately if you notice any of the following:

- slow or difficult breathing, chest tightness or congestion
- fever, chills or other signs of infection
- swelling of the face, ankles, feet or lower legs
- pain, numbness or heavy feeling in the legs
- unusually slow or very fast heart beat
- seizures (fits)
- depression or other severe mood or mental changes
- thoughts of suicide or self-harm
- difficulty in swallowing
- rash or itching of skin
- continuous uncontrollable eye movements
- loss of bladder (urine) control or other bladder problems
- severe vomiting, diarrhoea or constipation
- increase in sideways curvature of the spine (a type of spinal deformity called scoliosis).

The above side effects could be serious. You may need medical attention.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Some people may get other side effects of Lioresal Intrathecal. Some side effects can only be detected by tests, including changes to your blood pressure.

After being given Lioresal Intrathecal

Storage

Lioresal Intrathecal will be stored at hospital out of reach of children. It is kept in a cool dry place below 30°C. (room temperature).

Product description

What it looks like

Lioresal Intrathecal is packaged in clear glass ampoules. Each pack contains one 1 mL ampoule.

Lioresal Intrathecal is used to test your response to baclofen injection.

Ingredients

Lioresal Intrathecal contains 0.05 mg (50 micrograms) baclofen as the active ingredient.

The ampoules also contain sodium chloride and water for injections.

Sponsor

Lioresal Intrathecal is supplied in New Zealand by:

Novartis New Zealand Limited

PO Box 99102

Newmarket

Auckland 1149

New Zealand

Telephone 0800 354 335

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